Written Testimony of the
International Hearing Society
To the House Energy and Commerce Subcommittee on Health
In Opposition to
H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017
May 2, 2017

Dear Chairman Burgess, Ranking Member Green, and Members:

Thank you for the opportunity to provide comments on H.R. 1652, the Over-the-Counter Hearing Aid Act. The International Hearing Society (IHS) commends the Subcommittee and sponsors of the legislation for their interest in hearing health care issues, including exploring options for expanding access to those individuals who could benefit from the use of hearing aids but are not yet using them. As an association that represents hearing aid dispensing professionals, our members see the positive impact that hearing aid use and aural rehabilitation has on their patients, including their overall health and improved function in their daily lives and relationships. IHS supports the ultimate goal at stake here of increasing competition and reducing cost.

Respectfully, our society must stand in opposition to H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017. We take this position due to concerns that individuals are not able to accurately self-diagnose and self-treat their hearing impairment and there being a lack of associated evidence to the contrary; that federal preemption of state licensing laws will lead to an unregulated distribution market that will in turn lead to poor satisfaction, poor adoption, and patient harm; and the absence of professional involvement at any point during the process of over the counter (OTC) hearing aid acquisition, as proposed, compromise consumer safety and efficacy.

There is also ample evidence that recent innovations in the delivery of care, technology, and access are already moving the needle in the direction of greater acceptance of hearing aids while adhering to the reasonable and limited regulatory standards that exist today. Panelists at the Federal Trade Commission workshop held April 18th discussed these advancements at length. Just two weeks ago, CVS announced an expansion into the hearing healthcare delivery system through the establishment of hearing aid centers into 50 of its clinics and future clinic model.

The FDA Safety & Effectiveness Standards for OTC Products dictate that OTC products must meet the "same standards as prescription drugs, and consumers must be able to 1) self-diagnose, 2) self-treat, and 3) self-manage [the condition], which can be assessed through label comprehension studies and actual use studies."[i] As you may know, the recommendation for OTC hearing aids originated from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Science, Engineering, and Medicine (NASEM). However, in public forums, representatives of these groups have stated that their recommendations were made on the presumption that individuals are able to self-diagnose, self-treat, and self-manage their loss. OTC hearing aids do not pass the litmus test, and

consistent with FDA standards, it is IHS's position that any movement to create such a category must be predicated on the production of validated evidence that a consumer can reliably self-diagnose, self-treat, and self-manage his/her hearing loss. To date, the evidence contradicts this goal. A recent study – the first of its kind – conducted by AZ Marketing Research for Amplifon found that of individuals who had self-perceived mild or moderate hearing loss: only 1 in 4 individuals correctly assessed their hearing loss, 13% had an FDA Red Flag (condition requiring medical referral), 10% had no hearing loss, 37% had a more severe loss than what they self-reported, and 20% self-selected a hearing device (online hearing aid or personal sound amplifier) with an output above safe levels (120db+).[ii] Further, a self-diagnosis goes beyond just assessing the degree and type of hearing loss. Hearing loss is a symptom of an underlying medical or functional disorder. For example, someone with the symptom of hearing loss may have the diagnosis of a cholesteatoma, bilateral age-related hearing loss, impacted cerumen, an ear infection, otosclerosis, or a variety of other conditions. A self-administered pure-tone hearing test alone cannot provide a proper diagnosis, nor are individuals capable of reliably self-diagnosing the reason why they may be experiencing a hearing loss.

As proposed by H.R. 1652, a reliance on individuals' self-diagnosing and self-treating their "perceived" hearing loss is likely to result in their purchasing hearing aids unnecessarily or when they may have an underlying medical condition (thereby delaying care), or purchasing the wrong hearing aid for their loss. The physiology (and psychology) of hearing loss is unique to each individual. The proper evaluation of hearing loss involves several important tests to include a patient history and audiometry, as well as the identification of possible related medical conditions, speech testing, and an otoscopic evaluation – each of which require, by necessity, the involvement of a licensed professional. If hearing aids are appropriate, optimal outcomes depend upon the proper fit of the hearing aid, aural rehabilitation (counseling), and ongoing follow-up care. Consider this - according to a survey conducted by IHS in 2015 of hearing aid dispensing professionals, the average new hearing aid patient has at least five appointments with their provider within the first year. This demonstrates the level of professional attention necessary to achieve a satisfactory result.

The alternative – creating an over the counter hearing aid classification – would most certainly lead to patient harm and poor outcomes for the thousands, or perhaps millions, of individuals seeking hearing aids. And perhaps equally as concerning, these poor outcomes will lead to the widespread lowering of hearing aid adoption rates and use. We have seen this happen in Asian markets like in Japan where professional intervention is minimal and hearing aids are widely available over the counter. Japan has a 39% satisfaction rate (compared to 81% in the US) and a 14.1% adoption rate (compared to 30.2% in the US). Interestingly, at the same time the U.S. is considering lowering its standards, the International Organization for Standardization is looking to establish a Hearing Aid Fitting Management standard based on the U.S. model, which is considered the gold standard for safe and effective care. This work comes as the result of a request from South Korea, which lacks professional standards and consequently has low adoption and satisfaction rates.

In our increasingly socially-connected world, we know more about the experiences and opinions of our personal network (friends and family) than ever. According to the American Express Global Customer Service Barometer survey conducted in 2014, "When it comes to poor customer service experiences, nearly all (95%) consumers talk about them, with 60% reporting that they talk about these experiences all of the time. On average, consumers tell 8 people about their good experiences, and over twice as

many people (21) about their bad experiences." These statistics don't bode well for the concept of an OTC hearing aid market since we know that satisfaction and hearing aid use is tied to the involvement of the licensed provider and use of best practices.[iii]

IHS understands the intention of the legislation is to not bind a consumer to a licensed practitioner in the purchase of a device. However, we see the potential for many unintended harmful patient outcomes under the proposed model beyond just the implications described above. Specifically, the federal preemption of state licensing laws will lead to the natural development of an incompetent and unlicensed group of individuals opening up shop to sell, customize, and service individuals who have purchased OTC hearing aids from another source. It is presently a common occurrence that a consumer will take an internet hearing aid or personal sound amplifier to a hearing aid specialist or audiologist for assistance. The public will have no understanding of the difference between a licensed and non-licensed provider, and will undoubtedly be harmed by the lack of competency and standards, as well as sales tactics that come along with unregulated providers. At a meeting of the Hearing Industries Association in March 2017, Dr. Dan Blazer, co-chair of the NASEM Committee on Hearing Health Care for Adults expressed to an IHS representative that the intention of the committee's recommendation was not to create an unlicensed class of providers, yet H.R. 1652 would do just that. As a result, not only is the consumer at risk of receiving inappropriate, unsafe, and/or unethical care through an unscrupulous, incompetent, and unlicensed provider, but poor outcomes will erode consumer trust and create negative perceptions of hearing aid providers and hearing aids.

In 1986, the State of Colorado determined that the regulation of audiologists and hearing aid specialists was no longer needed because of a lack of complaints by consumers and subsequently eliminated professional licensure and all standards that went along with licensure. This action essentially created an OTC hearing aid marketplace in the state. The result of unregulated hearing aid sales spoke for itself. Within months unscrupulous, untrained, unlicensed, and incapable would-be sales people flocked to the state. These were people who could not get licensed previously or had their licenses revoked either in Colorado or in other states, or who were merely trying to make a quick dollar. They would open storefronts or operate out of their vehicles, but when a client needed services, they would often disappear. Many would hold seminars for the public promising phenomenal results, taking money from those in need, and not deliver on their promises. People with hearing loss, including the elderly, were hurt in these transactions both financially and psychologically, and the recovery, once licensure was reinstated, took several years. In its 1999 Sunset Review, the Colorado Department of Regulatory Agencies Office of Policy and Research stated, "This sunset review found that there is significant actual public harm by the unregulated practice of hearing aid sales," and as a result the department recommended continued regulation of hearing aid dealers.[iv, v] This is in spite of the fact that during the deregulation period - from 1986 through 1995 - the regulation of hearing aid sales had been governed by the state's Consumer Protection Act. Even with state oversight, licensure of those dispensing hearing aids was still deemed necessary.

The concept of reestablishing this model across the country, and with our most vulnerable population as the target, is of significant concern. Federal and state regulations governing who can dispense hearing aids and requirements associated with the sale are a necessary safeguard and must be maintained in order to prevent the widespread abuse and mistrust that would inevitably arise out of the establishment of an OTC hearing aid classification. Not to mention the lack of state-based consumer protections that

would no longer be afforded the patient who purchases an over the counter hearing aid. The mistakes corrected after Colorado's failed experiment should not be repeated on a nationwide scale.

Over time, the hearing aid dispensing community has worked diligently to improve patient satisfaction and acceptance of hearing aids as a solution, and most importantly build trust within their communities and with prospective and existing patients. Their efforts are reflected in the current satisfaction rates for hearing care providers (hearing aid specialists and audiologists). A recent study shows that 95% of owners and 87% of non-owners are satisfied with the health care providers they have seen in the last five years. The same study shows that satisfaction with hearing aids is high as well, with satisfaction at "91% for hearing aids obtained in the last year; 77% for hearing aids obtained 2-5 years ago; and 74% for hearing aids obtained 6 or more years ago." The overall satisfaction rate is at 81%.[vi] Comparatively, cellular telephone companies' (oftentimes affiliated with consumer electronics) satisfaction rates are on average 79%, with a maximum satisfaction rate of 81% in 2016.[vii] The aforementioned efforts by the hearing care provider community to build trust and a respected reputation is critical because of an overall wariness by individuals with hearing loss to obtain hearing aids due to stigma, vanity, and denial. Stigma being the number one reason that people choose not to seek out hearing aids is a difficult challenge, but IHS believes that other recommendations made by the NASEM to include increasing consumer education and awareness and engage primary care physicians can help move the needle in a positive way.

While the eyeglass analogy tends to be used in comparison to hearing aids - truly an apples and oranges comparison in terms of the complexity in identification, physiological and medical implications, and treatment of hearing loss - the regulation and delivery of eyeglasses and contacts can serve as a useful model for drawing the line between expanded competition and the overall lowering of cost, and patient safety. The current model allows for individuals to purchase eyeglasses and contacts from online and other retailers if they have a prescription from a licensed ophthalmologist or optometrist within the previous six months. This model ensures that the eyeglasses or contacts are appropriate for the patient/consumer, yet still allows for them to investigate the delivery model that will best meet their needs and shop around. If hearing aids were to be sold direct to the consumer, building in a requirement that the consumer obtain an order from a licensed professional within the previous six months that affirms the individual has had an audiometric evaluation and visual inspection of the ear, has mild to moderate hearing loss, and could benefit from the use of a hearing aid, coupled with FDA regulations governing the safety of the devices, would minimize patient safety and efficacy concerns. This model would create an informed consumer who could then explore all the options available to him/her, which would be a better alternative than the complete elimination of the hearing care provider in the process. Further, most hearing aid providers offer free hearing screenings, so this requirement would not add a cost barrier.

It is for the aforementioned reasons that the International Hearing Society opposes H.R. 1652 in its current form. IHS believes the creation of an FDA-approved classification of OTC hearing aids should only be considered following a comprehensive actual use study to validate whether individuals can reliably self-diagnose, self-treat and self-manage their hearing loss. If they cannot, such study should determine which mechanisms must be put into place to ensure safe and effective care, such as having an in-person hearing evaluation from a licensed provider (a hearing aid specialist, audiologist, or physician, preferably an otolaryngologist) within six months of purchasing a device over the counter. This model

will enable consumers to be informed consumers and make a decision on which treatment model they prefer once they fully understand their hearing loss and options. Finally, we would ask for a resolution to our concerns with full federal preemption of state licensing laws related to OTC hearing aids so that consumers can be assured that individuals who dispense, fit and modify OTC hearing aids are competent, held to an accepted standard, and that protections exist if they are harmed. Therefore, IHS respectfully asks that you delay further consideration of H.R. 1652 until the studies are completed and the appropriate model based on evidence be determined. Alternatively, IHS would be pleased to offer amendment language for the subcommittee's consideration.

IHS respectfully also suggests time be given to see through new initiatives that are being undertaken within the hearing healthcare field and marketplace, each of which can have a profound impact on hearing aid adoption rates before seeking to take the extreme step of legislating an over the counter hearing aid category. These initiatives, for which agreement was made at the December 2016 NASEM meeting to move forward, include a public awareness campaign, outreach to the medical community to promote hearing loss as an important health care issue, the establishment of standards for hearing aid outcomes and metrics for patients to use to assess their hearing ability, and creating consensus standards for community-based service providers. These are in addition to the other NASEM recommendations that are being implemented by individual organizations just as we are doing at IHS. Fortunately, hearing aid use, outcomes, and accessibility are presently on a positive trajectory. It would be a detriment to overall healthcare outcomes to place this positive momentum at risk at this time.

Thank you for your consideration. With questions or to discuss further, please contact IHS Government Affairs Director Alissa Parady at 734.522.7200 or aparady@ihsinfo.org.

Founded in 1951, the International Hearing Society represents hearing aid dispensing professionals worldwide, including dispensing audiologists, dispensing physicians, and the approximately 9,000 hearing aid specialists licensed in the U.S. presently. Hearing aid specialists dispense and provide professional services to approximately half of the non-VA hearing aid market, operate in both urban and rural areas, and often perform nursing home and home visits – delivering care to those in need, including those in remote locations. IHS promotes and maintains the highest possible standards for its members in the best interests of the hearing-impaired population they serve by conducting programs in competency accreditation, testing, education and training, and encourages continued growth and education for its members through advanced certification programs.

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[i] https://www.fda.gov/downloads/aboutfda/centersoffices/cder/ucm148055.pdf
[ii] http://www.hearingreview.com/2016/12/implications-counter-approach-hearing-healthcare-consumer-study/
[iii] "MarkeTrak VIII: The Impact of the Hearing Healthcare Professional on Hearing Aid User Success: Correlations between dispensing protocols and successful patient outcomes." Hearing Review, April 2010.
[iv] http://hermes.cde.state.co.us/drupal/islandora/object/co%3A4646
[v] Also known as hearing aid specialists, hearing instrument specialists, hearing aid dispensers, and hearing aid fitters.
[vi] http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/
[vii] http://www.theacsi.org/index.php?option=com_content&view=article&id=147&catid=&Itemid=212&i=Cellular+Telephones